

**Army Regulation 40–33
SECNAVINST 3900.38C
AFMAN 40–401(I)
DARPAINST 18
USUHSINST 3203**

Medical Services

The Care and Use of Laboratory Animals in DOD Programs

**Headquarters
Departments of the Army, Navy, Air Force,
Defense Advanced Research Projects
Agency, and the Uniformed Services
University of the Health Sciences
Washington, DC
10 November 2003**

UNCLASSIFIED

SUMMARY of CHANGE

AR 40-33/SECNAVINST 3900.38C/AFMAN 40-401(I)/DARPAINST 18/USUHSINST 3203

The Care and Use of Laboratory Animals in DOD Programs

This revision--

- o Changes the title of the regulation to reflect current areas of coverage and changes the series number to more accurately reflect the content.
- o Delineates the responsibilities of the Director, Defense Research and Engineering, the Secretary of the Army, the Director, DOD Veterinary Service Activity, the institutional official, the Institutional Animal Care and Use Committee, the principal investigator, and the attending veterinarian (paras 4a, 4c, 4d, 4e, 4f, 4g, and 4h).
- o Updates the responsibilities for the heads of Department of Defense components (para 4b).
- o Exempts extramural facilities accredited by the Association for the Assessment and Accreditation for Laboratory Animal Care, International, from initial site visits (para 5c(1)(c)).
- o Prohibits the wounding of dogs, cats, and nonhuman primates for medical or surgical training and their use in advanced trauma life support training (paras 5h(2) and 5h(3)).
- o Provides for the review of proposals involving the use of chimpanzees by the Interagency Animal Model Committee (para 6j(2)).
- o Adds policy for managing complaints concerning violations of animal care and use standards (para 7).
- o Requires the submission of a semiannual review report on facility inspection to the institutional official and prescribes the use of a new form for this purpose, DD Form 2856 (DOD Semiannual Program Review/Facility Inspection Checklist) (para 8a(1) and app D).
- o Specifies the requirement to release information to the public in an accessible database (para 9).
- o Adds an animal use protocol format for submitting proposals concerning animal use in Department of Defense programs (app C).

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Effective 10 December 2003

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Top of the SIGNATURE block

History. This publication is a major revision.

Summary. This regulation, as revised, is entitled “The Care and Use of Laboratory Animals in DOD Programs.” It delineates the Secretary of the Army as the DOD Executive Agent for Veterinary Services to develop and issue Service regulations to implement DOD Directive 3216.1. It creates uniform policies, procedures, and responsibilities among DOD components involved in the use of animals outlined in this regulation. This regulation references pertinent Federal statutes and regulations and other standards related to the care and use of animals. It establishes policies regarding the care and use of animals, whether performed by Department of Defense personnel or contract or grant recipients.

Applicability. This regulation applies to the Military Departments, the Uniformed Services University of the Health Sciences, and the Defense Agencies (hereafter referred to collectively as “DOD components”) that perform or sponsor activities using animals for research, education, training, or testing. This regulation is applicable during mobilization.

Proponent and exception authority.

The Army Surgeon General is the proponent of this regulation. The proponent has the authority to approve exceptions to this regulation that are consistent with controlling law and regulation. Proponents may delegate the approval authority, in writing, to a division chief under their supervision within the proponent agency that holds the grade of colonel or the civilian equivalent.

Army management control process. This regulation does not contain management control provisions.

Supplementation. Army supplementation of this regulation and establishment of command and local forms are prohibited without prior approval of the Office of the Surgeon General (DODVSA). Send requests for exception, with justification, through command channels to Office of the Surgeon General, ATTN: DODVSA, 5109 Leesburg Pike, Falls Church, VA 22041–3258. Other DOD component supplements will be approved according to individual component policies through the appropriate component offices listed in appendix B. If supplements are issued, DOD components will furnish one copy to the Office of the Surgeon General

(DODVSA), 5109 Leesburg Pike, Falls Church, VA 22041–3258.

Suggested improvements. Army users are invited to send comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications and Blank Forms) or by memorandum directly to the Office of the Surgeon General, ATTN: DODVSA, 5109 Leesburg Pike, Falls Church, VA 22041–3258. Other DOD users will submit their comments and suggested improvements through the individual component offices listed in appendix B to the address shown above.

Committee Continuance Approval. The DA Committee Management Officer concurs in the establishment of institutional animal care and use committees.

Distribution. This publication is available in electronic media only and is intended for command level B, C, D, and E for the Active Army, command level C for the Army National Guard of the United States (ARNGUS), and command level D for the U.S. Army Reserve (USAR). Navy: SNDL. Air Force: F. DARPA: Special. USUHS: Special.

*This regulation supersedes AR 70–18/SECNAVINST 3900.38B/AFR 169–2/DARPAINST 18/DNAINST 3216.1B/USUHSINST 3203, 1 June 1984, together with change 1, 1 August 1984.

UNCLASSIFIED

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Glossary

1. Purpose

a. This regulation sets forth policies, procedures, and responsibilities for the care and use of laboratory animals within Department of Defense (DOD) programs.

b. This regulation covers any live vertebrate animal that is being used or is intended for use in research, training, or testing, or for experimentation purposes.

c. This regulation does not cover animals used for ceremonial or recreational purposes, military working animals, and farm animals, such as, but not limited to, livestock or poultry, used or intended for use as food or fiber, or livestock or poultry used or intended for use in improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber.

2. References

Required and related publications and prescribed and referenced forms are listed in appendix A.

3. Explanation of abbreviations and terms

Abbreviations and special terms used in this regulation are explained in the glossary.

4. Responsibilities

a. The Director, Defense Research and Engineering (DDR&E), (acting for the Under Secretary of Defense for Acquisition and Technology) or his or her designee will—

(1) Issue policies and procedural guidance under DOD Directive 3216.1 concerning animal use consistent with all applicable Federal regulations and policies.

(2) Designate a DOD representative to the Interagency Research Animal Committee (IRAC); this veterinarian will be a veterinarian of appropriate rank, grade, and experience, and preferably a diplomate of the American College of Laboratory Animal Medicine (ACLAM).

(3) Establish the Joint Technical Working Group (Animal Use) (JTWG) to act in a central advisory capacity to the Armed Services Biomedical Research Evaluation and Management (ASBREM) Committee on all matters pertaining to the care and use of laboratory animals in DOD programs. The co-chairpersons of the ASBREM Committee will designate the chairperson of the JTWG.

b. The heads of the DOD components will—

(1) Establish appropriate mechanisms to implement and monitor compliance with this regulation and other applicable Federal statutes, policies, and guidelines.

(2) Provide members to the JTWG as requested and appointed by the DDR&E.

(3) Designate the appropriate oversight office(s) within DOD components (see appendix B) that will—

(a) Perform the headquarters-level administrative review of all proposals requiring the use of nonhuman primates (NHPs), dogs, cats, and marine mammals.

(b) Receive reports of protocol suspensions and significant deficiencies.

(c) Serve as reviewing and approving authorities of animal use proposals from extramural facilities proposing research under contract(s), award(s), or grant(s).

(4) Support and, as necessary, ensure the development of animal care and use training programs for researchers and members of Institutional Animal Care and Use Committees (IACUCs) and applicable certification programs for all personnel involved in the care, use, and treatment of animals.

c. The Secretary of the Army, as the DOD Executive Agent for Veterinary Services, will—

(1) In consultation with the other DOD components, develop, issue, and implement this regulation.

(2) Designate the Director, DOD Veterinary Service Activity (DODVSA) (a field operating agency of the Army, Office of the Surgeon General) as the consultant to the Assistant Secretary of Defense for Health Affairs (ASD(HA)) and the DDR&E for technical and professional matters related to this regulation.

d. The Director, DODVSA will serve as consultant to ASD(HA) and the DDR&E for technical and professional matters concerning this regulation.

e. The institutional official will—

(1) Ensure that DOD animal care and use programs and facilities conform to applicable standards, guidelines, and policies cited in this regulation. If there is a conflict between this regulation and the standards of humane care and use of animals as cited in the publications referenced in paragraph 6, the more stringent standard shall apply.

(2) Ensure that all research, education, training, or testing using animals is documented in an approved protocol.

(3) Appoint a duly constituted IACUC to monitor and ensure humane care and use of animals.

(4) Ensure that all deficiencies noted by the IACUC during semiannual reviews of animal care and use programs and facilities are corrected.

(5) Ensure that local animal care and use, procurement, and transportation policies and procedures comply with this regulation.

(6) Ensure that DOD organizations or facilities maintaining animals for use in research, testing, or training make

application for and maintain accreditation with the Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC) and that the animal care unit is adequately resourced.

(7) Support and, as necessary, develop animal care and use training programs, and encourage and resource appropriate certification for all personnel involved in the care, use, and treatment of laboratory animals.

f. IACUCs within DOD will—

(1) Review all proposals or protocols for DOD animal care and use programs conducted or sponsored by DOD components, organizations, or facilities.

(2) Ensure that proposals or protocols are submitted in the DOD animal use protocol format. (See app C.)

(3) Perform semiannual reviews of animal care and use programs and facilities. (See app D.)

(4) Perform other duties as listed in Title 9, Code of Federal Regulations.

g. The principal investigator (P.I.) will—

(1) Submit proposals or protocols in the DOD animal use protocol format.

(2) Ensure that protocols are executed as approved by the IACUC.

(3) Maintain accurate records and provide an audit trail of animal expenditures and use that correlates to the approved protocols.

h. The attending veterinarian will—

(1) Serve as a voting member of the IACUC and have direct or delegated responsibility for the animals at the facility.

(2) If employed on a part-time or consulting basis, provide a written program of veterinary care with a written list of regularly scheduled visits to the facility. The scheduled visits will be conducted with sufficient frequency to provide adequate veterinary care for the animals.

5. Policies and procedures

a. Decision to use animals. The inclusion of animals in DOD programs is the responsibility of DOD component and sub-level directors and commanders. The proponent of this regulation is not the authority for initiating and conducting programs that involve animals.

b. Other methods. Alternative methods to the use of animals must be considered and used if such alternatives produce scientifically valid or equivalent results to attain the research, education, training, and testing objectives.

c. Contracts and grants.

(1) DOD components that sponsor animal care and use programs under a grant or contract will ensure that—

(a) Extramural research proposals using live animals are administratively reviewed and approved by a DOD veterinarian trained or experienced in laboratory animal medicine and science prior to release of funding for animal research.

(b) All contract or grant facilities subject to inspection by the U.S. Department of Agriculture (USDA) must provide the most recent inspection report (USDA, Animal and Plant Health Inspection Service (APHIS) Form 7008 (Animal Care Inspection Report)) to the DOD oversight component office. Prior to release of funding for animal research, a DOD veterinarian will review the USDA Animal Care Inspection Reports. Electronic review of inspection reports is permissible. During the term of the award, a DOD veterinarian will review annually the most recent USDA Animal Care Inspection Reports.

(c) A DOD veterinarian trained and experienced in laboratory animal medicine will conduct an initial site visit to evaluate animal care and use programs and facilities at all institutions conducting DOD-sponsored research using nonhuman primates, dogs, cats, or marine mammals. Additionally, this veterinarian will perform site visits to any institution conducting DOD-sponsored research using animals where research procedures, program, or facility conditions necessitate. The timing of the initial visit is at the discretion of the DOD veterinarian conducting the visit and is based upon an administrative review of the proposed research, the institution's animal care and use program, its AAALAC accreditation status, its Public Health Service Office of Laboratory Animal Welfare assurance status, and its USDA Animal Care Inspection Reports. For OCONUS sites, similar information is required.

(d) Any facility receiving a DOD-funded contract or grant for animal-based research notifies the DOD component sponsor and has a site inspection within 30 days of notification of loss of AAALAC accreditation or notification that the facility is under USDA investigation. Site inspections for cause will evaluate and ensure the adequacy of animal care and use in DOD-sponsored programs and provide recommendations to the sponsoring DOD component about continued funding support.

(e) All procurement contracts contain the Defense Acquisition Regulation Supplement clause DFARS 252.235-7002, "Animal Welfare".

(f) All grants, cooperative agreements and other agreements contain appropriate animal welfare terms and conditions as specified by agency policy and procedures.

(2) Extramural contractors that propose to use animals in DOD-sponsored programs will submit all pertinent information required in the DOD animal use protocol format in their contract proposal.

d. Centralized review and oversight of NHPs.

(1) A headquarters-level administrative review of all NHP protocols will be conducted at the appropriate DOD-component oversight office by a veterinarian trained or experienced in laboratory animal medicine and science to ensure conformance with all applicable Federal regulations and policies. A DOD component may delegate this responsibility to another DOD component for purposes of efficiency and consolidation of functional offices. (See app B.)

(2) Proposals intending to use chimpanzees require further review and approval by the Interagency Animal Model Committee that coordinates national priorities for research utilization of this species.

(3) The JTWG will encourage coordination and cooperation in the transfer of Government-owned NHPs between facilities to maximize conservation and proper utilization.

e. AAALAC accreditation. DOD organizations or facilities maintaining animals for use in DOD programs will—

(1) Attain and maintain accreditation with the AAALAC.

(2) Provide the Director, Biosystems, ODDR&E, Suite 9030, 1777 North Kent Street, Rosslyn, VA 22209, with documentation of any change in AAALAC accreditation status.

(3) Explain the absence of accreditation and submit a plan of action and milestones to obtain accreditation.

f. Composition and training of the IACUC.

(1) The IACUC will be constituted in accordance with chapter I, subchapter A, Animal Welfare, part 2, section 2.31(b)-IACUC Membership and additionally will—

(a) Be composed of a minimum of five members.

(b) Have a primary and an alternate nonaffiliated member. (This requirement is intended to facilitate community representation at each IACUC meeting, facility inspection, and semiannual program review.)

(c) Have at least one non-scientific member.

(2) All IACUC member(s) and alternate(s) will—

(a) Receive initial training that consists of at least 4 hours of training in regulatory responsibilities and proper techniques of the animal protocol review process.

(b) Receive at least 4 additional hours of training on humane care and ethical issues dealing with animal use.

(c) Be either a Federal employee, covered under the Intergovernmental Personnel Act (IPA), or a consultant consistent with the requirements established by Section 3109, Title 5, United States Code (5 USC 3109).

g. Suppliers. Animal must be obtained from suppliers licensed by the USDA under Federal Animal Welfare Regulations (Title 9, CFR, Chapter I, Subchapter A, Parts 1, 2, and 3), unless specifically exempted from licensing requirements by such regulations.

h. Prohibited uses. Prohibited uses for dogs, cats, nonhuman primates, and marine mammals are the following:

(1) Research conducted for development of biological, chemical, or nuclear weapons.

(2) Inflicting wounds with any type of weapon(s) to conduct training in surgical or other medical treatment procedures.

(3) Advanced trauma life-support (ATLS) training.

i. Training uses. DOD organizations or facilities wishing to conduct training programs using animals will—

(1) Ensure training protocols, submitted in the DOD animal use protocol format (see app C), are reviewed and approved by a duly constituted IACUC. Organizations without an IACUC should contact the appropriate component office (see app B) for guidance and assistance.

(2) Ensure adequate care for animals.

(3) Have the animal housing facilities inspected and approved by a veterinarian prior to the receipt of animals.

(4) Restrict the use of dogs, cats, nonhuman primates, or marine mammals to research and training not listed in paragraph 5h.

j. Use of DOD facilities. The use of animals in a collaborative effort with or on behalf of other Federal, DOD, or civilian agencies in DOD facilities will comply fully with this regulation.

k. Animal programs in foreign countries. Activities covered by this regulation performed or sponsored in foreign countries will be conducted in accordance with the regulations and standards of the host country and applicable U.S. statutory requirements. If differences exist between U.S. and host country regulations or standards, unless prohibited by the host country, the more stringent standard shall apply.

6. Statutes, regulations, standards, and guidelines

a. Public Law 101-511, Department of Defense Appropriations Act, FY 1991, Section 8019 (10 USC 2241) prohibits the purchase or use of dogs, cats, or NHPs for inflicting wounds from any type of weapon(s) in order to conduct training in surgical or other medical treatment procedures.

b. The Laboratory Animal Welfare Act of 1966 (7 USC 2131 et seq.), as amended, and implementing regulations promulgated by the USDA (Title 9, Code of Federal Regulations, Parts 1-4 (9 CFR 1-4)) require licensing of dealers, identification of animals, maintenance of records, submission of reports, establishment of an IACUC, and compliance with standards for the humane handling, care, treatment, and transportation of animals by dealers and research facilities.

c. The Endangered Species Act of 1973 (16 USC 1531–1543; and 50 CFR Parts 10–14, 17, and 217–227), as amended, and implementing regulations provide a program, under the Department of the Interior, for conserving threatened and endangered species. This act requires the U.S. Government to acquire import/export permits, maintain records, make reports, and perform inspections on the care and handling of endangered, threatened, and conserved species covered by the act. Additional guidance is found in the Convention on International Trade in Endangered Species of Wild Fauna and Flora and 50 CFR 23.

d. The Marine Mammal Protection Act of 1972 (16 USC 1361–1384; and 50 CFR Parts 10–14, 18, and 216), as amended, and implementing regulations promulgated by the National Oceanic and Atmospheric Administration, provide a program for protection of marine mammals. This act requires the acquisition of permits, maintenance of records, submission of reports, and inspections on the care and handling of marine mammals.

e. The Lacey Act (Section 42, Title 18, United States Code (18 USC 42)); and Title 50, Code of Federal Regulations, Part 16, Subpart B (50 CFR 16, Subpart B)), as amended, prohibits the importation of certain wild animals or their eggs if the Secretary of the Interior determines that they are injurious to humans or a detriment to the interests of agriculture or to other specified national interests. These wild animals and their eggs are identified within the Lacey Act.

f. Regulations on the use of harmful or dangerous viruses, serums, toxins, and other similar agents used in animal research facilities producing or testing biological products are provided for in Section 154, Title 21, United States Code (21 USC 154) and Part 117, Title 9, Code of Federal Regulations (9 CFR 117).

g. Regulations on the import and export of animals, their intra- and interstate shipment, and the requirements for their quarantine and inspection are presented in the following documents: 5 USC 301; 19 CFR 120; 21 USC 111–113, 114a, 115–117, 120–126, and 151–158; 9 CFR 71–97 and 122; 42 USC 216 and 264–272; and 42 CFR 71–72.

h. Additional guidance on housing, caring for, and using laboratory animals is provided for in the “Guide for the Care and Use of Laboratory Animals,” 1996, published by the National Academy Press, Washington, DC.

7. Management of complaints

a. Personnel with complaints of violation(s) of this regulation may report such violations to one or all of the following:

- (1) IACUC chairperson/IACUC member.
- (2) Attending veterinarian.
- (3) Facility commander or institutional official.
- (4) Inspector General.

b. The IACUC will review and, if warranted, investigate complaints involving animal use or noncompliance with applicable laws, regulations, directives, or guidelines. Protocol suspensions and significant deficiencies shall be reported to the appropriate DOD component oversight office. (See app B.)

8. Reports

a. At least once every 6 months, all IACUCs within DOD will submit a written evaluation of the animal care and use program to the institutional official. The report must contain a description of the nature and extent of the research facility’s adherence to Subchapter A of the Animal Welfare Act Regulations, identify specifically any departure from Subchapter A, and state the reasons for each departure.

(1) The evaluation will be documented using DD Form 2856. Additional information is provided in appendix D.

(2) As a minimum, the report consists of DD Form 2856. DD Form 2856 is used as the basis of the program and facility review (minority views must be included, if applicable), and describes any facility or program deficiencies, the corrective actions taken or planned, and timelines where appropriate.

(3) Any failure to adhere to the plan and schedule that results in a significant deficiency that is or may be a threat to the health or safety of the animals will be reported within 15 business days by the institutional official for forwarding to the appropriate DOD component oversight office. (See app B for addresses.)

(4) After the institutional official signs the report, it is returned to the IACUC and retained for a minimum of 3 years.

b. DOD organizations will submit APHIS Form 7023 (Annual Report of Research Facility) to the USDA as required and in accordance with USDA implementing regulations of the Animal Welfare Act.

c. All DOD organizations using animals subject to this regulation will submit copies of each APHIS Form 7023, and other data as directed, to the proper DOD component oversight office. (See app B.)

d. All organizations using animals in accordance with the provisions of this regulation will prepare and submit summaries of their research in the format specified by the JTWG for inclusion in the DOD Biomedical Research Database.

9. Release of information

DOD components will report all animal-based protocols for public release to the Defense Technical Information Center (DTIC).

10. Navy distribution

The Navy has determined that the guidance in this regulation is intended for:

- a.* A1 (Immediate Office of the Secretary) (ASSTSECNAV MRA and ASSTSECNAV RES).
- b.* A2A (Department of the Navy Staff Offices) (Chief of Naval Research and Naval Criminal Investigative Services only).
- c.* A3 (Chief of Naval Operations).
- d.* 21A (Fleet Commanders).
- e.* 22A (Fleet Commanders).
- f.* 23 (Force Commanders).
- g.* 24 (Type Commanders).
- h.* E3A (Laboratory Research).
- i.* E8A (Criminal Investigation Service).
- j.* FHI (Medical and Surgery).
- k.* FKA1G (Sea Systems Command).

Appendix A

References

Section I

Required Publications

This section contains no entries.

Section II

Related Publications

AFI 31–202

Military Working Dog Program <http://www.e-publishing.af.mil/pubs/>

AR 11–2

Management Control

AR 40–905/SECNAVINST 6401.B/AFI 48–131

Veterinary Health Services

AR 70–45

Scientific and Technical Information Program

AR 190–12

Military Police Working Dogs

AR 700–81/AFR 400–8/NAVINST 10570.1/MCO 105–0.1

DOD Dog Program

DA Pam 190–12

Military Working Dog Program

42 CFR 71–72

Foreign Quarantine; Interstate Shipment of Etiologic Agents www.access.gpo.gov/nara/cfr/

50 CFR Part 23

Endangered Species Convention www.access.gpo.gov/nara/cfr/

DOD Directive 3216.1

Use of Laboratory Animals in DOD Programs www.dtic/whs/directives/

DOD FAR

DOD Federal Acquisition Regulation Supplement web1.deskbook.osd.mil/

Guide for the Care and Use of Laboratory Animals

1996 edition or succeeding revised editions (Copies of this publication may be obtained from the National Academy Press, 2101 Constitution Avenue NW, Washington, DC 20418.) www.nap.edu

PL 101–511, section 8019

Department of Defense Appropriations Act for Fiscal Year 1991 (10 USC 2241 note)

SECNAVINST 3900.41

Procurement, Transport, and Maintenance of Marine Mammals <http://neds.nebt.daps.mil/Directives>

Convention on International Trade in Endangered Species of Wild Fauna and Flora

(CITES) <http://www.cites.org>

5 USC 3109

Employment of Experts and Consultants: Temporary or Intermittent www.gpoaccess.gov/uscode/index.html

7 USC 2131 et seq. and 9 CFR parts 1–4

The Laboratory Animal Welfare Act www.gpoaccess.gov/uscode/index.html

16 USC 1531–1543 and 50 CFR Parts 10–14, 17, and 217–227

The Endangered Species Act www.gpoaccess.gov/uscode/index.html

16 USC 1361–1384 and 50 CFR Parts 10–14, 18, 23, and 216

The Marine Mammal Protection Act www.gpoaccess.gov/uscode/index.html

18 USC 42 and 50 CFR Part 16, Subpart B

The Lacey Act www.gpoaccess.gov/uscode/index.html

42 USC 216 and 264–272

Quarantine and Inspection www.gpoaccess.gov/uscode/index.html

Section III

Prescribed Forms

DD Form 2856

DOD Semiannual Program Review/Facility Inspection Checklist. (Prescribed in para 8a(1) and app D) (Available from the OSD Web site at www.dior.whs.mil/ICDHOME/DDEFORMS.HTM.)

Section IV

Referenced Forms

APHIS Form 7008

USDA Animal Care Inspection Report

APHIS Form 7023

Annual Report of Research Facility (This form supersedes USDA Form VS 18–23.) APHIS Form 7008 and APHIS Form 7023 may be obtained from the local regional office of the APHIS/USDA or by contacting APHIS/USDA/Animal Care, 4700 River Road, Riverdale, MD 20737–1234; telephone number: (301) 734–7833; fax: (301) 734–4978; e-mail: ace@usda.gov; Internet address: <http://www.aphis.usda.gov/ac/>)

Appendix B

DOD Component Offices

B-1. Oversight offices

The following DOD component agencies have been designated as oversight offices.

Commander

U.S. Army Medical Research and Materiel Command

ATTN: MCMR-RCQ-AR

504 Scott Street – Fort Detrick

Frederick, MD 21702-5012

HQ, AFMOA/SGOT

110 Luke Avenue, Room 400

Bolling Air Force Base, DC 20332-7050

Chief, Naval Bureau of Medicine and Surgery

Assistant Chief for Operational Medicine and Fleet Support (MED-02)

ATTN: Special Assistant for Veterinary Medicine (MED-26E)

2300 E Street NW

Washington, DC 20372-5300

President

Uniformed Services University of the Health Sciences

ATTN: Director, Department of Laboratory Animal Medicine

4301 Jones Bridge Road

Bethesda, MD 20814

Commander

U.S. Army Chemical and Biological Defense Command

ATTN: SCBRD-RTL

Veterinary Support Team

Aberdeen Proving Ground, MD 21010-5423

Director

Armed Forces Institute of Pathology

14th and Alaska Avenue NW

Washington, DC 20306-6000

Commander – Army Medical Department Center and School

Clinical Investigations Regulatory Office

ATTN: MCCS-GCI

1608 Stanley Road, Suite 2

Fort Sam Houston, TX 78234-5055

Commander

U.S. Army Special Operations Command

ATTN: Command Surgeon

Fort Bragg, NC 28307-5000

Office of the Director for Defense Research and Engineering

Room 3E808

3080 Defense Pentagon

Washington, DC 20301-3080

Director

Defense Advanced Research Projects Agency

ATTN: Administrative Office

3701 North Fairfax Drive

Arlington, VA 22203-1714

Defense Threat Reduction Agency
8725 John J. Kingman Drive
MSG 6201
Fort Belvoir, VA 22060-6201

B-2. Functions of the oversight offices

These oversight offices carry out the responsibilities listed in paragraph 4*b*(3) of this regulation, and they will provide guidance and assistance upon request.

Appendix C

DOD Animal Use Protocol Format

C-1. Requirements

All DOD animal use protocols must use the format shown in this appendix. This protocol format includes requirements of the Animal Welfare Act Regulations, the Guide, and other applicable Federal regulations and DOD directives.

C-2. Protocol cover sheet

Before the protocol is submitted for IACUC review, at least three signatures are required on the protocol cover sheet (fig C-1). They must include those of the Principal Investigator (P.I.); either the department or division chief or the scientific review committee chairperson; and the individual performing the statistical review.

-
- I. Name of Facility
 - II. Proposal Number
 - III. Title
 - IV. Principal Investigator(s)/Division/Phone/E-mail
 - a. Printed Name (First Name, MI, Last Name); Title; Division
 - b. Signature; Date (YYYYMMDD); Phone, Fax
 - V. Scientific/Division Review/Phone/E-mail
 - a. Printed Name (First Name, MI, Last Name); Title; Division
 - b. Signature; Date (YYYYMMDD); Phone, Fax
 - VI. Statistical Review/Division/Phone/E-mail
 - a. Printed Name (First Name, MI, Last Name); Title; Division
 - b. Signature; Date (YYYYMMDD); Phone, Fax
 - VII. Attending Veterinarian/Division/Phone/E-mail
 - a. Printed Name (First Name, MI, Last Name); Title; Division
 - b. Signature; Date (YYYYMMDD); Phone, Fax

Figure C-1. DOD animal use protocol cover sheet

a. Scientific/division review. This signature verifies that the animal use proposal received appropriate scientific peer review and is consistent with good scientific practice.

b. Attending veterinarian. The Animal Welfare Act Regulations require that an attending veterinarian must be consulted in the planning of procedures/manipulations that may cause more than slight or momentary pain or distress, even if relieved by anesthetics or analgesics.

c. Statistical review. A person knowledgeable in biostatistics is required to review all proposals to ensure that the number of animals used is appropriate to obtain sufficient data and/or is not excessive, and the statistical design is appropriate for the intent of the study.

C-3. DOD animal use protocol format

a. The format shown in figure C-2 is designed to be used with several word-processing programs on a personal computer as a “fill-in-the-blank” type of document. It is available electronically through the appropriate DOD component oversight office listed in appendix B. Each paragraph and subparagraph in the format must have a response. Title headings do not require a response. Portions of the protocol format that are not applicable will be marked “N/A.” There are no space limitations for the responses. Pertinent standing operating procedures (SOPs) or similar documents that are readily available to the IACUC may be referenced to assist in the description of specific procedures.

PROTOCOL TITLE
PRINCIPAL INVESTIGATOR(S)
CO-INVESTIGATOR(S)
I. NON-TECHNICAL SYNOPSIS
II. BACKGROUND
II.1. Background
II.2. Literature Search for Duplication
II.2.1. Literature Source(s) Searched
II.2.2. Date of Search
II.2.3. Period of Search
II.2.4. Key Words of Search
II.2.5. Results of Search
III. OBJECTIVE/HYPOTHESIS
IV. MILITARY RELEVANCE:
V. MATERIALS AND METHODS
V.1. Experimental Design and General Procedures
V.1.1. Experiment 1
V.1.2. Experiment 2
V.2. Data Analysis
V.3. Laboratory Animals Required and Justification
V.3.1. Non-animal Alternatives Considered
V.3.2. Animal Model and Species Justification
V.3.3. Laboratory Animals
V.3.3.1. Genus and Species
V.3.3.2. Strain/Stock
V.3.3.3. Source/Vendor
V.3.3.4. Age
V.3.3.5. Weight
V.3.3.6. Sex
V.3.3.7. Special Considerations
V.3.4. Number of Animals Required (By Species)
V.3.5. Refinement, Reduction, Replacement
V.3.5.1. Refinement
V.3.5.2. Reduction
V.3.5.3. Replacement
V.4. Technical Methods
V.4.1. Pain/Distress Assessment
V.4.1.1. APHIS Form 7023 Information (See attending veterinarian for assistance)
V.4.1.1.1. Number of animals:
V.4.1.1.1.1. Column C: __ (Animal #)
V.4.1.1.1.2. Column D: __ (Animal #)
V.4.1.1.1.3. Column E: __ (Animal #)
V.4.1.2. Pain Relief/Prevention
V.4.1.2.1. Anesthesia/Analgesia/Tranquilization
V.4.1.2.2. Pre- and Post-procedural Provisions
V.4.1.2.3. Paralytics
V.4.1.3. Literature Search for Alternatives to Painful Procedures
V.4.1.3.1. Sources Searched
V.4.1.3.2. Date of Search
V.4.1.3.3. Period of Search
V.4.1.3.4. Key Words of Search
V.4.1.3.5. Results of Search
V.4.1.4. Unalleviated Painful/Distressful Procedure Justification
V.4.2. Prolonged Restraint
V.4.3. Surgery

Figure C-2. DOD animal use protocol format

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- V.4.3.1. Pre-operative Provisions
 - V.4.3.2. Procedure
 - V.4.3.3. Post-operative Provisions
 - V.4.3.4. Location
 - V.4.3.5. Surgeon
 - V.4.3.6. Multiple Major Survival Operative Procedures
 - V.4.3.6.1. Procedures
 - V.4.3.6.2. Scientific Justification
 - V.4.4. Animal Manipulations
 - V.4.4.1. Injections
 - V.4.4.2. Biosamples
 - V.4.4.3. Adjuvants
 - V.4.4.4. Monoclonal Antibody Production
 - V.4.4.5. Animal Identification
 - V.4.4.6. Behavioral Studies
 - V.4.4.7. Other Procedures
 - V.4.4.8. Tissue Sharing
 - V.4.5. Study Endpoint
 - V.4.6. Euthanasia
 - V.5. Veterinary Care
 - V.5.1. Husbandry Considerations
 - V.5.1.1. Study Room
 - V.5.1.2. Special Husbandry Provisions
 - V.5.1.3. Exceptions
 - V.5.2. Veterinary Medical Care
 - V.5.2.1. Routine Veterinary Medical Care
 - V.5.2.2. Emergency Veterinary Medical Care
 - V.5.3. Environmental Enrichment
 - V.5.3.1. Enrichment Strategy
 - V.5.3.2. Enrichment Restriction
 - VI. STUDY PERSONNEL QUALIFICATIONS AND TRAINING
 - VII. BIOHAZARD/SAFETY
 - VIII. ENCLOSURES: Enclosures such as IACUC policies on adjuvants, monoclonal antibody production, tissue sharing, food and/or water restriction, prolonged restraint, pathology addenda, and pain assessment criteria may be included at the discretion of the P.I. unless directed by the IACUC.
 - IX. ASSURANCES: The law specifically requires several written assurances from the Principal Investigator. Please read and sign the assurances as indicated.

As the Principal Investigator on this protocol, I acknowledge my responsibilities and provide assurances for the following:

A. Animal Use: The animals authorized for use in this protocol will be used only in the activities and in the manner described herein, unless a modification is specifically approved by the IACUC prior to its implementation.

B. Duplication of Effort: I have made every effort to ensure that this protocol is not an unnecessary duplication of previous experiments.

C. Statistical Assurance: I assure that I have consulted with a qualified individual who evaluated the experimental design with respect to the statistical analysis, and that the minimum number of animals needed for scientific validity will be used.

D. Biohazard/Safety: I have taken into consideration and made the proper coordinations regarding all applicable rules and regulations concerning radiation protection, biosafety, recombinant issues, and so forth, in the preparation of this protocol.

Figure C-2. DOD animal use protocol format—Continued

E. Training: I verify that the personnel performing the animal procedures/manipulations/observations described in this protocol are technically competent and have been properly trained to ensure that no unnecessary pain or distress will be caused to the animals as a result of the procedures/manipulations.

F. Responsibility: I acknowledge the inherent moral, ethical and administrative obligations associated with the performance of this animal use protocol, and I assure that all individuals associated with this project will demonstrate a concern for the health, comfort, welfare, and well-being of the research animals. Additionally, I pledge to conduct this study in the spirit of the fourth "R" namely "Responsibility", which the DOD has embraced for implementing animal use alternatives where feasible and conducting humane and lawful research.

G. Scientific Review: This proposed animal use protocol has received appropriate peer scientific review and is consistent with good scientific research practice.

H. Painful Procedures: (A signature for this assurance is required by the Principal Investigator if the research being conducted has the potential to cause more than momentary or slight pain or distress even if an anesthetic or analgesic is used to relieve the pain and/or distress.)

I am conducting biomedical experiments, which may potentially cause more than momentary or slight pain or distress to animals. This potential pain and/or distress WILL or WILL NOT (circle one or both, if applicable) be relieved with the use of anesthetics, analgesics, and/or tranquilizers. I have considered alternatives to such procedures; however, I have determined that alternative procedures are not available to accomplish the objectives of this proposed experiment.

(PRINT)First Name, MI, Last Name of Principal Investigator

Signature Date (YYYYMMDD)

Figure C-2. DOD animal use protocol format—Continued

b. Some information may be added to the format to meet local needs. However, all labeled paragraphs and subparagraphs will remain in the same relative order. The added information will be similar or complementary to the information requested. Other types of requirements specific to a given Service, command, or locale (such as budgeting information, local coordinating requirements, or specific scientific review requirements, and so forth) can be added by placing them in front or behind the standard format.

C-4. Protocol format with completion aids

The format shown in figure C-3 is the same protocol format as in figure C-2. Explanations have been added to aid in completing the protocol proposal.

PROTOCOL TITLE: Title must include species of animal(s) used in research.

PRINCIPAL INVESTIGATOR(S)

CO-INVESTIGATOR(S)

I. NON-TECHNICAL SYNOPSIS: Provide a brief, narrative description of the proposal that is easily understood by a high school graduate. Include animal use in your description. (NOTE: This information may be used to complete the DOD Annual Report to Congress.)

II. BACKGROUND

II.1. Background: Include a brief statement of the requirement or need for the information being sought. Lengthy explanations are not required. Typically, the literature or the experience that led to the proposal will be briefly reviewed, references cited, and a description of the general approach provided.

II.2. Literature Search for Duplication: This search must be performed to prevent unnecessary duplication of previous experiments. A search of the Biomedical Research Database (BRD) is required. In addition, a search of EITHER the Federal Research in Progress (FEDRIP) OR the Computer Retrieval of Information of Scientific Projects (CRISP) database is required. Requirements for additional searches are at the discretion of the IACUC.

II.2.1. Literature Source(s) Searched

II.2.2. Date of Search

II.2.3. Period of Search

II.2.4. Key Words of Search

II.2.5. Results of Search: Provide a narrative description of the results of the literature search.

III. OBJECTIVE/HYPOTHESIS: State the objective of this protocol or the hypothesis to be accepted or rejected. (NOTE: This information will be used to complete the DOD Annual Report to Congress.)

IV. MILITARY RELEVANCE: Provide a brief and succinct military justification for the research with regard to military needs and mission requirements. If applicable, state the Science and Technology Objective (STO) that this work supports.

V. MATERIALS AND METHODS

V.1. Experimental Design and General Procedures: This section includes an explanation of experimental design. Technical methodology need not be described in this section, rather, it should be described under paragraph 5.D., Technical Methods. Provide a complete description of the proposed use of animals to include a summary table of the experimental groups. Succinctly outline the formal scientific plan and direction of experimentation. If several experiments or sequential studies are to be included in the protocol, describe the experimental design of each separate experiment in sub-parts to this section. The length and detail required in this section depends largely on the complexity of the study. A clearly understandable description of the numbers of animals and their distribution into experimental groups is essential. The number requested must equal the minimum number required to complete the study yet be sufficient to yield meaningful results. The minimum number includes animals necessary for controls or technique development, and so forth. Inclusion of a summary table or flow chart showing the distribution of animals by experimental group is highly recommended. The total number of animals required for the study is listed in section V.3.4.

V.1.1. Experiment 1

Figure C-3. DOD animal use protocol format with completion aids

V.1.2. Experiment 2

V.2. Data Analysis: List the statistical test(s) planned or describe the strategy intended to evaluate the data. Describe the statistical methodology used to determine group size and total number of animals. A power-based assessment of the sample size is the preferable method of determining the minimum number that is likely to yield significant results with given alpha and beta errors, estimated effect size and expected variability. Be certain to include animals necessary for controls or technique development, and so forth.

V.3. Laboratory Animals Required and Justification

V.3.1. Non-animal Alternatives Considered: State all non-animal alternatives (for example, computer modeling, in vitro cell culture work) that were considered. Explain why animals are needed.

V.3.2. Animal Model and Species Justification: Provide a scientific justification for the choice of animal model(s). What physiological and morphological characteristics does this animal possess that make it the best possible model? If less sentient (invertebrate versus vertebrate) animal models were considered but not chosen, explain why.

V.3.3. Laboratory Animals

V.3.3.1. Genus and Species

V.3.3.2. Strain/Stock: If inbred or specialized animals are required, use proper terminology. (See the attending veterinarian for assistance.)

V.3.3.3. Source/Vendor: Provide a preferred source for the animals. Animals will be legally obtained from suppliers licensed by the U.S. Department of Agriculture (USDA) in accordance with Code of Federal Regulations, Title 9, Animals and Animal Products, Chapter 1, Subchapter A, Animal Welfare, Parts 1, 2, and 3. (See the attending veterinarian for assistance.)

V.3.3.4. Age

V.3.3.5. Weight

V.3.3.6. Sex

V.3.3.7. Special Considerations: List specialized requirements for animals here (for example, simian immunodeficiency virus or herpes antibody free, Pasteurella free, and so forth).

V.3.4. Number of Animals Required (By Species): The number of animals stated here must correspond exactly to that described in section V.1. If, during the completion of the protocol, additional animals are needed owing to technical or unavoidable circumstances, or to exploit a serendipitous finding, follow IACUC procedures for requesting approval of additional animals.

V.3.5. Refinement, Reduction, Replacement (3 Rs): Investigators are required to consider the 3 Rs when preparing an animal use research protocol. In the paragraphs below, describe all provisions in this protocol that refine, reduce, or replace the use of animals. Discuss what provisions were considered and why they were not chosen. If N/A is used, explain why.

V.3.5.1. Refinement: Procedures or measures taken to eliminate or minimize pain or distress in the animal(s) or enhance animal well-being. Examples of refinement include but are not limited to the use of analgesia to decrease pain or distress, the use of remote telemetry, which decreases the distress of restraint, or the use of adjusted early experimental endpoints. In addition to listing refinements, list

Figure C-3. DOD animal use protocol format with completion aids—Continued

refinement alternatives that would allow you to meet your scientific objectives and were considered but not adopted. Explain why they were not adopted.

V.3.5.2. Reduction: Procedures or measures taken to reduce the number of animals used. Examples of reduction include but are not limited to the use of shared or historical control groups, preliminary screening in non-animal systems, and innovative statistical packages. In addition to listing reductions that will be used, list reduction alternatives that would allow you to meet your scientific objectives and were considered but not adopted. Explain why they were not adopted.

V.3.5.3. Replacement: Procedures or measures that eliminate the use of animals. Examples of replacements include but are not limited to the use of non-animal models or less sentient animal species. In addition to listing replacements that will be used, also list replacement alternatives that would allow you to meet your scientific objectives and were considered but not adopted. Explain why they were not adopted.

V.4. Technical Methods: This information must be presented in sufficient detail, documented or referenced, so that the IACUC can adequately review the procedure, obtain a clear understanding of what is to be done and how the animals will be handled, and make a reasonable determination as to whether this proposed use of laboratory animals is in compliance with DOD regulations, guidelines, and Federal law.

V.4.1. Pain/Distress Assessment: The law defines a painful procedure as one that would “reasonably be expected to cause more than slight or momentary pain or distress in a human being to which that procedure was applied; that is, pain in excess of that caused by injections or other minor procedures.” If a procedure may involve pain or distress, even if relieved by anesthetics or analgesics, the P.I. must consult with the attending veterinarian.

V.4.1.1. APHIS Form 7023 Information: (See your attending veterinarian for assistance.) The protocol must contain an estimate of the number of animals that will be counted in columns C, D, and E of the APHIS Form 7023, Annual Report of Research Facility. Columns C, D and E represent specific pain categories. (See below paragraphs, V.4.1.1.1.1.-3.) The animal should be listed in the column corresponding to the most painful or distressful procedure experienced by the animal. It is possible for one protocol to have animals listed in several columns. For instance, control animals may be placed in Column C while experimental animals may be placed in Column D, depending upon the nature of the protocol. Reflect use of more than one species of animals in a duplicate table. The total numbers reflected in these three columns will add up to the number of animals requested for the entire protocol in paragraph V.3.4.

V.4.1.1.1. Number of Animals

V.4.1.1.1.1. Column C: __ (animal #)

Examples of research procedures/manipulations that would require an animal to be placed in Column C are studies involving not more than slight or momentary pain and/or distress in a human being to which that procedure is applied.

V.4.1.1.1.2. Column D: __ (animal #)

Examples of procedures/manipulations that would require an animal to be placed in Column D are procedures where anesthesia or analgesia will be administered to avoid or effectively relieve pain or distress. General anesthesia given for surgical procedures, or the use of analgesia or anti-inflammatory agents are examples of this category.

V.4.1.1.1.3. Column E: __ (animal #)

Examples of procedures/manipulations that would require an animal to be placed in Column E are procedures in which alleviation of pain or distress are contraindicated for a scientifically justifiable reason such as the experimental results are likely to be confounded if drugs relieving pain or distress were

Figure C-3. DOD animal use protocol format with completion aids—Continued

administered. Detailed justification for putting animals into this category is required below in paragraph V.4.1.4.

V.4.1.2. Pain Relief/Prevention

V.4.1.2.1. Anesthesia/Analgesia/Tranquilization: Describe the methods or strategies planned to effectively relieve or prevent pain or distress if the study will cause more than slight or momentary pain or distress. If pain/distress relief/prevention is planned, specify agents to be used and when these agents will be given (pre-emptive or post-procedural). Provide agent, dosage, and frequency of administration.

V.4.1.2.2. Pre- and Post-procedural Provisions: Describe the provisions for both pre- and post-procedural care, including provisions for post-procedural observations and frequency of observations. (Information concerning pre- and post-surgical care should be listed in paragraphs V.4.3.1 and V.4.3.3). If analgesics are used for pain/distress relief, provide the frequency of administration, observational criteria utilized to determine if animals are experiencing pain or distress, and the location for the post-procedural care.

V.4.1.2.3. Paralytics: The use of paralytic agents without anesthesia is prohibited. Describe the monitoring method that will be used to ensure adequate depth of anesthesia while the animal is under the influence of the paralytic agent.

V.4.1.3. Literature Search for Alternatives to Painful or Distressful Procedures: Respond N/A if the animals will experience not more than momentary or slight pain or distress and are placed in column C of APHIS Form 7023. (See paragraph V.4.1.1.)

V.4.1.3.1. Source(s) Searched: Examples are AGRICOLA, MEDLINE, BIOSIS, Altweb, and so forth.

V.4.1.3.2. Date of Search

V.4.1.3.3. Period of Search

V.4.1.3.4. Key Words of Search: Examples are pain, surgery, alternatives, LD 50, analgesia, anesthesia, death as an endpoint, distress, species of animal(s) to be used, name of painful or distressful experimental procedure, and so forth.

V.4.1.3.5. Results of Search: Provide a narrative summary of the results of the literature search for alternatives. The Animal Welfare Act specifically states that the P.I. must provide a narrative description of the methods and sources, e.g., the Altweb (Johns Hopkins Center for Alternatives to Animal Testing), MEDLINE, Life Sciences Abstracts, AGRICOLA, and BIOSIS) that he/she used to determine that alternatives to the painful procedure were not available. Discuss alternatives (those that would meet your scientific objectives) considered but not chosen. The alternatives literature search MUST be performed even when animals are placed in Column D and the pain or distress is alleviated through the use of analgesics or anesthetics.

V.4.1.4. Unalleviated Painful/Distressful Procedure Justification: Procedures that cause more than slight or momentary pain or distress that is not alleviated through the effective use of anesthetics or analgesics must be justified on a scientific basis in writing by the P.I. This paragraph must be completed if there are ANY animals in this protocol that will experience unalleviated pain or distress.

V.4.2. Prolonged Restraint: Describe (period of restraint, method, and timing of animal observations, habituation/training of animal to restraint device) and justify in detail any prolonged restraint greater than 12 hours for nonhuman primates or in accordance with IACUC policy for other species. Examples of restraint methods are primate chairs, restraint boards, metabolism cages, and so forth. This section is not intended for short-term actions such as rabbit restraint for bleeding, and so forth.

V.4.3. Surgery: Major survival operative procedures on non-rodent species will be conducted only in dedicated facilities intended for that purpose, and operated and maintained under aseptic conditions.

Figure C-3. DOD animal use protocol format with completion aids—Continued

Non-survival operative procedures do not require a dedicated facility, but they should be performed using surgical gloves, mask, and clean instruments. Additionally, the surgical site should be clipped and cleaned prior to surgery. Major survival rodent surgery does not require a dedicated facility but it must be performed using aseptic technique; that is, aseptic patient preparation, surgical gloves, mask, and sterile instruments. A major operative procedure is defined as a procedure that penetrates and exposes a body cavity, or causes substantial or permanent impairment of physical or physiological function.

V.4.3.1. Pre-Surgical Provisions: Describe the provisions for pre-surgical care, including provisions for pre-surgical observations and frequency of pre-surgical observations. If analgesics are utilized for pain or distress relief, provide the time schedule for administration, observational criteria utilized to determine if animals are experiencing pain/distress, and the location for the pre-surgical care.

V.4.3.2. Procedure: Describe in detail any surgical procedures planned.

V.4.3.3. Post-Surgical Provisions: Describe the provisions for post-surgical care, including provisions for post-surgical observations, frequency of post-surgical observations and criteria for early euthanasia owing to surgical complications or pain that cannot be relieved. If analgesics are utilized for pain or distress relief, provide the time schedule for administration, observational criteria utilized to determine if animals are experiencing pain/distress, and the location for the post-surgical care.

V.4.3.4. Location: Give the location/room number for the proposed surgical procedure.

V.4.3.5. Surgeon

V.4.3.6. Multiple Major Survival Operative Procedures: The principal investigator must scientifically justify multiple major survival operative procedures performed on the same animal.

V.4.3.6.1. Procedures

V.4.3.6.2. Scientific Justification

V.4.4. Animal Manipulations: Describe any injections, sampling procedures, or other manipulations of the animals necessary for the study. A reference or SOP may be furnished to the IACUC to document a particular procedure in lieu of a detailed description.

V.4.4.1. Injections: Information must include route of injection, dosage, frequency, volume injected, needle size, and anatomic injection site.

V.4.4.2. Biosamples: Examples include cerebrospinal fluid taps, blood sampling, and biopsies. List volumes taken, sampling site, frequency of sampling, needle size, and method of sampling. Procedures performed or biosamples obtained during a necropsy need not be described here.

V.4.4.3. Adjuvants: List any adjuvants used and the plan for their use. Provide a scientific justification for the use of Complete Freund's Adjuvant (CFA) and discuss why other less reactive adjuvants cannot be used. Provide dosages, volumes, route, number of injection sites, and injection locations. Specify frequency and method of injection site monitoring and include a response plan (for example, alternative endpoint and veterinary medical treatment) in the event of an adverse reaction.

V.4.4.4. Monoclonal Antibody (MAbs) Production: Provide a scientific justification for *in vivo* MAbs production. What *in vitro* methods of MAbs production were considered but not used? For *in vivo* MAbs production, specify the priming agent, animal monitoring frequency, number and frequency of abdominal taps, and fluid replacement therapy. Include a response plan (for example, alternative endpoint and veterinary medical treatment) in the event of an adverse reaction.

V.4.4.5. Animal Identification: Describe the method of animal identification used in this study. Examples include microchips, tattoos, ear tags, and cage cards.

Figure C–3. DOD animal use protocol format with completion aids—Continued

V.4.4.6. Behavioral Studies: Fully describe the use of aversive stimuli, food or water restriction, and so forth, that would affect the study animals. Include methods of monitoring physiologic or behavioral indexes, including criteria (for example, weight loss or state of hydration) for temporary or permanent removal of the animal from the study. Provide an appropriate scientific justification for this type of behavior modification. An IACUC policy may be included where applicable.

V.4.4.7. Other Procedures: Describe all procedures which have not been explained in other sections of this proposal that will be performed while conducting this research. Examples include electrocardiograms, radiology, and aerosol exposure.

V.4.4.8. Tissue Sharing: List what tissues will be shared, with whom, and for what purpose.

V.4.5. Study Endpoint: State the projected study endpoint for the animals (for example, recovery and return to issue pool, euthanasia, or death without early euthanasia). Indicate whether recovery, euthanasia, or death is expected; and the specific plan for determining when the animal experimentation phase will be stopped. The P.I. must ensure that unnecessary pain or distress is prevented by carefully considering "When is the experimental question answered?" so that the animals can be expeditiously removed from the study. Define specific criteria that will be used to determine study endpoint (for example, weight loss, loss of locomotion and significant lowering of body temperature, decreased food or water consumption, and decreased activity). Specifically address and scientifically justify any proposal in which critically ill or moribund animals are allowed to die as a result of the experimental procedures without the benefits of veterinary medical treatment or early euthanasia. Explain the plan for the disposition of surviving animals or animals removed from the study prior to its completion.

V.4.6. Euthanasia: If applicable, discuss the euthanasia method. The Animal Welfare Act defines euthanasia as "humane destruction of an animal by a method that produces rapid unconsciousness and subsequent death without evidence of pain or distress, or a method that utilizes anesthesia produced by an agent that causes painless loss of consciousness and subsequent death." The current American Veterinary Medical Association (AVMA) guidelines for euthanasia must be followed. Exceptions to the AVMA guidelines will be considered by the IACUC on a case-by-case basis. If requested, the attending veterinarian will assist in selecting the best method for euthanasia.

V.5. Veterinary Care: If requested, the attending veterinarian of the facility will assist principal investigators with preparing this section.

V.5.1. Husbandry Considerations: Federal regulations require that animal housing and living conditions must be appropriate to their species and contribute to their health and comfort. Briefly describe animal husbandry to include routine animal observations, caging methods, feed and water provisions, environmental parameters, sanitation schedule, and light cycle.

V.5.1.1. Study Room: Where will the experimental procedure be conducted? Will the animal be housed in this room for more than 12 hours?

V.5.1.2. Special Husbandry Provisions: Examples include micro-isolators, metabolic cages, food and water restriction.

V.5.1.3. Exceptions: Describe any deviations/exceptions to *The Guide for the Care and Use of Laboratory Animals*, the Animal Welfare Act regulations, or IACUC policy that have an impact on animal housing space, feeding, and sanitation. Deviations/exceptions must be justified by the P.I. and approved by the IACUC.

V.5.2. Veterinary Medical Care

V.5.2.1. Routine Medical Care: Describe the routine veterinary medical care. State if the animals will be observed daily or more frequently. Indicate what will happen if the animal becomes ill or debilitated during

Figure C-3. DOD animal use protocol format with completion aids—Continued

the study and requires evaluation. List the criteria used for health evaluation while the animals are on study (for example, weight loss, ruffled fur, dehydration, decreased activity, and hunched body position). Include a response plan (for example, alternative early endpoint, and veterinary medical treatment) in the event of debilitating illness or an adverse reaction.

V.5.2.2. Emergency Veterinary Medical Care: Describe emergency veterinary medical care.

V.5.3. Environmental Enrichment

V.5.3.1. Enrichment Strategy: Discuss enrichment provided to animal species listed in this protocol.

V.5.3.2. Enrichment Restriction: Provide written justification for restricting enrichment programs or activity programs of dogs, cats, or nonhuman primates. Single housing of nonhuman primates and dogs without sensory contact with conspecifics must also be justified and approved by the IACUC.

VI. STUDY PERSONNEL QUALIFICATIONS AND TRAINING: List the names, qualifications and training by procedure of all personnel working with animals assigned to this protocol. Personnel performing observations, procedures and/or manipulations described in the protocol must be identified and appropriately trained and qualified to perform these procedures. Contact the attending veterinarian for assistance with this requirement.

VII. BIOHAZARD/SAFETY: Provide a list of any potential biohazards associated with the chosen animal model and this research proposal (for example, viral agents, toxins, radioisotopes, oncogenic viruses, and chemical carcinogens). Describe safety precautions and programs designed to protect personnel from biohazards associated with this research and any surveillance procedures in place to monitor potential exposures.

VIII. ENCLOSURES: Enclosures such as IACUC policies on adjuvants, monoclonal antibody production, tissue sharing, food and/or water restriction, prolonged restraint, pathology addenda, and pain assessment criteria may be included at the discretion of the P.I. unless directed by the IACUC.

Figure C-3. DOD animal use protocol format with completion aids—Continued

C-5. Personnel qualifications.

a. A Study Personnel Qualifications/Training table must be included in section VI of the protocol description. The table format is preferred by the IACUC for ease of reviewing the protocol. The table will contain the following four column headings:

(1) Name of the activity (for example, the procedure, observation, or manipulation to be performed, such as the venous catheterization of a dog).

(2) Name of the person performing the activity.

(3) Qualifications of the person performing the activity (for example, ALAT, 2 years experience).

(4) Training of the person performing the activity (for example, Canine Procedures Workshop, 1999).

b. Itemize each activity being performed in the protocol. List per species if there are multiple species in the protocol. If more than one individual is performing the activity, list each individual separately.

Appendix D

Instructions for Use of DD Form 2856 (DOD Semiannual Program Review/Facility Inspection Checklist)

D-1. The checklist and the inspection report

The IACUC must complete the DOD Semiannual Program Review/Facility Checklist during the IACUC semi-annual program review and facility inspection in accordance with Title 9, Code of Federal Regulations, Subchapter A, Part 2, Subpart C. Individual checklists must be kept on file in the IACUC office but do not require attachment to the finished IACUC Semiannual Program Review/Facility Inspection Report.

D-2. Use of the form

The use of the form is self-explanatory; simply place a checkmark in the most appropriate category for each item on the inspection list. A sample completed DD Form 2856 is shown in figure D-1.

DOD SEMIANNUAL PROGRAM REVIEW/ FACILITY INSPECTION CHECKLIST				
ORGANIZATION	DATE OF REVIEW (YYYYMMDD)			
DOD Animal Facility	2002 Jul 19			
Completion of this checklist by the IACUC during the semi-annual program review and facility inspection is mandatory. Mark X in the most appropriate category for each item. KEY: A = Acceptable; M = Minor deficiency; S = Significant deficiency (is or may be a threat to animal health or safety).				
CATEGORIES	A	M	S	N/A
SECTION I - INSTITUTIONAL POLICIES AND RESPONSIBILITIES				
1. MONITORING THE CARE AND USE OF ANIMALS				
a. INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE	X			
b. ANIMAL CARE AND USE PROTOCOLS	X			
c. PHYSICAL RESTRAINT	X			
d. MULTIPLE MAJOR SURGICAL PROCEDURES	X			
e. FOOD OR FLUID RESTRICTION	X			
2. PERSONNEL QUALIFICATIONS AND TRAINING	X			
3. OCCUPATIONAL HEALTH AND SAFETY OF PERSONNEL				
a. HAZARD IDENTIFICATION AND RISK ASSESSMENT		X		
b. PERSONNEL TRAINING	X			
c. PERSONAL HYGIENE	X			
d. FACILITIES, PROCEDURES, AND MONITORING	X			
e. ANIMAL EXPERIMENTATION INVOLVING HAZARDS	X			
f. PERSONAL PROTECTION	X			
g. MEDICAL EVALUATION AND PREVENTIVE MEDICINE FOR PERSONNEL	X			
SECTION II - ANIMAL ENVIRONMENT, HOUSING, AND MANAGEMENT				
4. PHYSICAL ENVIRONMENT				
a. MICROENVIRONMENT AND MACROENVIRONMENT		X		
b. HOUSING	X			
c. SPACE RECOMMENDATIONS	X			
d. TEMPERATURE AND HUMIDITY	X			
e. VENTILATION	X			
f. ILLUMINATION		X		
g. NOISE	X			
5. BEHAVIORAL MANAGEMENT				
a. STRUCTURAL ENVIRONMENT	X			
b. SOCIAL ENVIRONMENT	X			
c. ACTIVITY	X			
6. HUSBANDRY				
a. FOOD	X			
b. WATER	X			
c. BEDDING	X			
d. SANITATION	X			
e. WASTE DISPOSAL	X			
f. PEST CONTROL	X			
g. EMERGENCY, WEEKEND, AND HOLIDAY CARE	X			
7. POPULATION MANAGEMENT				
a. IDENTIFICATION AND RECORDS	X			
b. GENETICS AND NOMENCLATURE	X			

DD FORM 2856, AUG 2002

Figure D-1. Sample completed DD Form 2856

CATEGORIES	A	M	S	N/A
SECTION III - VETERINARY MEDICAL CARE				
8. ANIMAL PROCUREMENT AND TRANSPORTATION	X			
9. PREVENTIVE MEDICINE				
a. QUARANTINE, STABILIZATION, AND SEPARATION	X			
b. SURVEILLANCE, DIAGNOSIS, TREATMENT, AND CONTROL OF DISEASE	X			
10. SURGERY	X			
11. PAIN, ANALGESIA, AND ANESTHESIA	X			
12. EUTHANASIA	X			
SECTION IV - PHYSICAL PLANT				
13. FUNCTIONAL AREAS	X			
14. CONSTRUCTION GUIDELINES				
a. CORRIDORS	X			
b. ANIMAL ROOM DOORS	X			
c. EXTERIOR WINDOWS	X			
d. FLOORS	X			
e. DRAINAGE	X			
f. WALLS	X			
g. CEILINGS	X			
h. HEATING, VENTILATION, AND AIR CONDITIONING (HVAC)	X			
i. POWER AND LIGHTING		X		
j. STORAGE AREAS	X			
k. NOISE CONTROL	X			
l. FACILITIES FOR SANITIZING MATERIALS	X			
15. FACILITIES FOR ASEPTIC SURGERY	X			
REMARKS				
3a. Risk assessment documentation partially complete. 4a. Room appears overcrowded/cluttered. 4f. Light flickering in Room 3. 14i. Light cover cracked in Room 15.				

DD FORM 2856 (BACK), AUG 2002

Figure D-1. Sample completed DD Form 2856—Continued

D-3. Evaluation guidelines

The DOD Semiannual Program Review/Facility Checklist was created using the National Research Council's 1996 *The Guide for Care and Use of Laboratory Animals* (Guide) as a template. Refer to the corresponding section of the Guide for more information on evaluation guidelines.

Glossary

Section I

Abbreviations

ASD(HA)

Assistant Secretary of Defense for Health Affairs

CONUS

continental United States

DAR

Defense Acquisition Regulation

DDR&E

Director, Defense Research and Engineering

DOD

Department of Defense

DODD

Department of Defense Directive

DTIC

Defense Technical Information Center

FAR

Federal Acquisition Regulation

OCONUS

outside the continental United States

RDT&E

research, development, test, and evaluation

SOP

standing operating procedure

STO

science and technology objective

USDA

U.S. Department of Agriculture

USUHSINST

Uniformed Services University of the Health Sciences Instruction

Section II

Terms

Accredited

Refers to accreditation of animal care and use programs and facilities by the Association for the Assessment and Accreditation of Laboratory Animal Care. The accreditation process is designed to provide a mechanism that ensures a high regard for animal welfare and enhances the quality of scientific research that uses experimental animals.

Alternative methods

Any system or method that covers one or more of the following:

- a.* Replacing the use of laboratory animals altogether.
- b.* Reducing the number of animals required.
- c.* Refining an existing procedure or technique to minimize the level of stress endured by the animal.

Animal

Any live vertebrate animal that is being used or is intended for use in research, education, training, or testing.

Approved source

Refers to dealers who provide animals for research, testing, and/or education and are either USDA-approved or USDA-exempted.

Centralized administrative review

A review performed by a laboratory animal veterinarian assigned to or working on behalf of the appropriate component's headquarters. The reviewer will determine if the DOD protocol format has been properly completed and will ensure that animal resources are shared and conserved when appropriate.

Clinical investigations

All activities directed toward clinical research conducted principally within medical treatment facilities. The Clinical Investigations Program is part of the Defense Health Program of the Assistant Secretary of Defense for Health Affairs and is supported by Major Force Program 8 funds.

Commander

Laboratory or unit commander, institute director, or other official having equivalent authority.

Consultant

A senior U.S. Army laboratory animal medicine veterinarian who acts in an advisory capacity to the Army Surgeon General on matters concerning laboratory animal medicine and on use of laboratory animals in DOD programs.

Dealer

Any person who, in commerce, for compensation or profit, delivers for transportation (or transports, except as a carrier), buys, sells, or negotiates the purchase or sale of animals.

DOD Component Office

Applies to the Office of the Secretary of Defense, the Military Departments, the Chairman of the Joint Chiefs of Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DOD Field Activities and all other organizational entities in the Department of Defense (hereafter referred to collectively as "the DOD Components").

DOD-sponsored program

Any study, proposal, or design for animal experimentation or demonstration in research, education, training, or testing conducted or funded by appropriation, grant, award, loan, contract, or cooperative research and development agreement.

Endangered species

A species or subspecies of mammal or non-mammal listed as "endangered" under the Endangered Species Act.

Exhibition

The use of animals, including working, recreational, or ceremonial animals, in displays, demonstrations, or ceremonies.

Injurious wildlife

Any wildlife for which a permit is required under the Lacey Act before being imported into or shipped between the continental United States and Alaska, Hawaii, the Commonwealth of Puerto Rico, or any possessions of the United States.

Institutional official

The individual who is authorized to legally commit on behalf of a research facility that the requirements of Title 9, Code of Federal Regulations, Subchapter A, Parts 1, 2, and 3 will be met.

Instructional programs

All educational and training activities, except training of ceremonial and recreational animals and training associated with military working animals or survival skills training.

Marine mammal

Mammals that are morphologically adapted to the marine environment (including sea otters and members of the orders Sirenia, Pinnipedia, and Cetacea) or primarily inhabit the marine environment (for example, polar bears).

Minority opinion

A belief or judgment based on evidence insufficient to produce complete certainty and which represents the view of the smaller part of a group; that is, less than one-half of the whole group.

Non-human primate

Any non-human member of the highest order of mammals, including prosimians, monkeys, and apes.

Principal investigator

An employee of a research facility, or other person associated with a research facility, responsible for a proposal to conduct research and for the design and implementation of research involving animals.

Reduction

Procedures or measures taken to reduce the number of animals used.

Refinement

Procedures or measures taken to eliminate or minimize pain or distress in the animal or enhance animal well-being.

Replacement

Procedures or measures that eliminate the use of animals.

Research, development, test, and evaluation

All activities which form the RDT&E program of the Director, Defense Research and Engineering, and are supported by Major Force Program 6 funds.

Research facility

Any school (except an elementary or secondary school), institution, organization, or person that uses or intends to use live animals in research, tests, experiments, or instructional programs.

Significant deficiency

A deficiency, which in the judgment of the IACUC and the institutional official, is or may be a threat to the health or safety of the animals (reference Title 9, Code of Federal Regulations, Subchapter A).

Threatened species

A species of mammal or non-mammal listed as “threatened” under the Endangered Species Act.

Training

A requirement of the Animal Welfare Act Regulations, which states that all personnel participating in the use of animals under an IACUC-approved protocol receive appropriate training in humane methods of animal maintenance and experimentation, limiting pain and/or distress of the animal, proper use of anesthetics, analgesic and tranquilizers, deficiency reporting, and utilization of services available to provide information on alternatives to the use of live animals in research and prevention of unnecessarily duplicative research.

Section III**Special Abbreviations and Terms****AAALAC**

Association for the Assessment and Accreditation of Laboratory Animal Care, International

ACLAM

American College of Laboratory Animal Medicine

AFI

Air Force Instruction

AFR

Air Force Regulation

APHIS

Animal and Plant Health Inspection Service

ASBREM

Armed Services Biomedical Research Evaluation and Management

AVMA

American Veterinary Medical Association

AWIC

Animal Welfare Information Center

BRD

Biomedical Research Database

CFA

Complete Freund's Adjuvant

CRISP

Computer Retrieval of Information of Scientific Projects

DARPAINST

Defense Advanced Research Projects Agency Instruction

DNAINST

Defense Nuclear Agency Instruction

DOD-FAR

Department of Defense Federal Acquisition Regulation

DODVSA

Department of Defense Veterinary Service Activity

FEDRIP

Federal Research in Progress

IACUC

Institutional Animal Care and Use Committee

IRAC

Interagency Research Animal Committee

JTWG

Joint Technical Working Group

Mabs

monoclonal antibodies

NHP

nonhuman primate

P.I.

principal investigator

SECNAVINST

Secretary of the Navy Instruction

VMD

Veterinary Medicine Division

3 Rs

refine, reduce, replace

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PAGES SET: 34

DATA FILE: C:\Wincomp\sueswi.fil

DOCUMENT: AR 40-33

SECURITY: UNCLASSIFIED

DOC STATUS: NEW PUBLICATION